



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Kevin K. Covey; Kelly J. Confirmation No. 8259  
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Bertagnole  
Serial No.: 10/008,243  
Filed: November 7, 2001 Customer No.: 28863  
Examiner: George C. Manuel  
Group Art Unit: 3762  
Docket No.: 1023-015US01  
Title: EASY-TO-USE ELECTRODE AND PACKAGE

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CERTIFICATE UNDER 37 CFR 1.8: I hereby certify that this correspondence is being deposited with the United States Post Service, as First Class Mail, in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313-1450 on August 11, 2005.

By: 

Name: Patricia Cygan

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicants respectfully request a Pre-Appeal Brief Request for Review, based upon the following grounds:

1. The Examiner made clear errors in rejections of claims, including the following errors:
  - a. The Examiner's Office Actions failed to include a full and reasoned explanation, as required by the Administrative Procedure Act and case law. In re Lee, 61 USPQ2d 1430, 1432-33 (Fed. Cir. 2002).
  - b. The Examiner based rejections in the Final Office Action upon new grounds that were not necessitated by amendments made by Applicants, and gave Applicants no opportunity to respond to those grounds. MPEP 706.07(a).

2. The Examiner omitted one or more essential elements needed for a prima facie rejection, including the following errors:

- a. Rejections under 35 U.S.C. §§ 102 and 103 failed to disclose one or more claimed elements.
- b. Rejections under 35 U.S.C. § 103 failed to be supported by a teaching, suggestion or motivation to combine the references. E.g., In re Dembiczak, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

Some of the details of the Examiner's errors are set forth below. For simplicity, Applicants focus upon the pending independent claims. By setting forth these clear grounds for error, Applicants do not assert that these are the only errors that the Examiner has made, nor do they waive any arguments that may be asserted in a Appeal Brief.

#### Claim 1

Claim 1 is an independent claim to a device.

In an Office Action dated July 12, 2004, the Examiner rejected claim 1 under 35 U.S.C. § 102(b) and (e) as being anticipated by Belt et al. (U.S. Patent No. 4,420,078) and Janae et al. (U.S. Patent No. 6,675,051). In an office action dated December 23, 2004, the Examiner rejected claim 1 as being anticipated by Costanzo (U.S. Patent No. 3,407,818), as well as by Belt and Janae.

In an Amendment dated March 21, 2005, Applicants amended Claim 1 to include elements of claim 4, and Applicants canceled claim 4. The elements of claim 4 were clearly not disclosed or suggested by Costanzo, Belt or Janae. Costanzo and Belt failed to disclose or suggest an external defibrillator, as recited in claim 1, as amended. Janae failed to disclose or suggest: (1) an anchor that fastens a pouch to the external defibrillator, and (2) a handle that, when pulled, causes the handle to move away from the anchor and tear the pouch to provide access to the electrode contained within the pouch. Each of these elements had been previously recited in claim 1 or claim 4.

In response to Applicant's Amendment of March 21, 2005, the Examiner issued a Final Office Action dated May 11, 2005, asserting entirely new grounds for rejection of claim 1. The new ground was based upon: (1) a different statute than had been urged previously, the Examiner

relying upon section 103 instead of section 102, (2) a different reference, the Examiner relying upon Freeman et al. (U.S. Patent No. 5,462,157) and not upon Costanzo, Belt or Janae, and (3) a new analysis of the claimed elements in light of the reference. The new grounds for rejection were not necessitated by Applicants' Amendment, because the elements of claim 1 as amended had been recited previously.

The Examiner made the rejection of May 11, 2005, final. Applicants have had no opportunity to respond to these grounds for rejection.

Furthermore, the rejection is clearly erroneous on its merits. Freeman does not disclose any anchor that fastens a pouch to an external defibrillator, as recited in claim 1, as amended. The Examiner referred to a structure in Freeman that fastens an electrode to a defibrillator, but claim 1 as amended clearly recites a pouch as an element distinguishable from an electrode.

In addition, the Examiner's failed to make a proper showing for rejection of a claim under section 103 based upon a single reference. "Even when obviousness is based upon a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). The Examiner made no such showing.

#### Claims 17, 28 and 53

Claim 17 is an independent claim to a device, claim 28 is an independent claim to a method and claim 53 is an independent claim to a method. Claims 17, 28 and 53 involve similar recited elements. In an Amendment dated March 21, 2005, Applicants amended claims 17, 28 and 53 to recite a "ring-shaped" handle. Applicants also canceled claims 21, which previously had recited a handle of having a ring shape.

In Office Actions dated July 12, 2004 and December 23, 2004, the Examiner cited references, none of which disclosed a ring-shaped handle. In the Final Office Action dated May 11, 2005, the Examiner rejected claims 17, 28 and 53 under 35 U.S.C. § 103 based upon two references: Walters et al. (U.S. Patent No. 6,048,640), which the Examiner had previously cited, and McNamee (U.S. Patent No. 4,566,129), which the Examiner had not previously cited. By the Examiner's own admission, Walters does not disclose a ring-shaped handle.

Applicants have been given no opportunity to respond to the rejections based upon McNamee. Furthermore, McNamee clearly does not disclose a ring-shaped handle. On the contrary, the McNamee ring-shaped elements are tamper indicators designed to fracture, not handles. Col.3, line 46 to col. 4, line 10. The Examiner's suggestion that McNamee shows a ring element as assisting in the opening of a package is clearly erroneous.

Further, the Examiner failed to provide a factual basis for asserting that one skilled in the art would be motivated to includes a McNamee tamper indicator as a ring-shaped handle on a pouch containing a defibrillation electrode.

#### Claims 35 and 41

Claim 35 is an independent claim to a device and Claim 41 is an independent claim to a method. Claims 35 and 41 involve similar recited elements. In an Amendment dated March 21, 2005, Applicants amended claims 35 and to recite a "non-zero" angle. Applicants' remarks of March 21, 2005 demonstrate how claims 35 and 41, as amended, distinguished claims 35 and 41 from the cited references. In particular, claims 35 and 41 recited a human figure printed on a defibrillation electrode, with the human figure "oriented on the defibrillation electrode at an angle relative to the defibrillation electrode, wherein the angle is non-zero such so that when the defibrillation electrode is applied to a patient with the head of the patient and the head of the human figure in the same direction, the defibrillation electrode will be oriented on the patient at the angle, wherein the angle defines proper placement of the defibrillation electrode on the patient for defibrillation therapy.

In the Final Office Action dated May 11, 2005, the Examiner has simply ignored the recited "non-zero" element.

#### Claim 47

Claim 47 is an independent claim to a device. Claim 47 recites a device comprising a right defibrillation electrode including a first instructive picture, and a left defibrillation electrode including a second instructive picture. As claimed, the first instructive picture includes a right electrode symbol on a first human figure, the first human figure oriented in a first direction relative to the right defibrillation electrode, and the second instructive picture includes a left

electrode symbol on a second human figure, the second human figure oriented in a second direction relative to the left defibrillation electrode. In the previous response, Applicants amended claim 47 on September 10, 2004, to specify that the first direction is different than the second direction.

The references cited by the Examiner, including Bishay et al. (U.S. Patent No. 5,951,598) and Nova (U.S. Patent Application No. 2003/0114885), show electrodes printed with human figures, the orientation of the human figures on the electrodes being the same for both electrodes, and not different, as recited in claim 47. Applicants pointed out the distinction in Remarks dated May 24, 2004, September 10, 2004 and March 21, 2005, but the Examiner has never addressed Applicants' arguments or the deficiencies of the applied references with respect to claim 47.

### CONCLUSION

For at least the above reasons, the rejections of the pending claims are clearly deficient, both factually and legally. Applicants request a review and a panel decision that promptly resolves the issues in Applicants' favor and eliminates the need for an Appellate Brief.

Date:

Aug. 11, 2005

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